

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Filed PCT/PTO 13 DEC 2004
PCT/JP2003/007463



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| Applicant's or agent's file reference 663830 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/JP2003/007463 | International filing date (day/month/year) 12 June 2003 (12.06.2003) | Priority date (day/month/year) 12 June 2002 (12.06.2002) |
| International Patent Classification (IPC) or national classification and IPC C12N 15/12, 1/19, 1/21, 5/10, C07K 7/06, C12P 21/02, C07K 16/32, A61K 38/17, 39/00, 39/395, 31/7088, A61P 35/00 | | |
| Applicant SUGIYAMA, Haruo | | |

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|----|--|
| 1. | This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. |
| 2. | This REPORT consists of a total of <u>6</u> sheets, including this cover sheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of _____ sheets. |
| 3. | This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application |

| | |
|--|---|
| Date of submission of the demand 23 October 2003 (23.10.2003) | Date of completion of this report 02 March 2004 (02.03.2004) |
| Name and mailing address of the IPEA/JP Facsimile No. | Authorized officer Telephone No. |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
 These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 21, 25

because:

☒ the said international application, or the said claims Nos. 21, 25
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See supplemental sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.1

Claims 21 and 25 pertain to methods for the
treatment of the human body.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|------------------|-----|
| Novelty (N) | Claims | 1-2, 4-15, 22-24 | YES |
| | Claims | 3, 16-20 | NO |
| Inventive step (IS) | Claims | | YES |
| | Claims | 1-20, 22-24 | NO |
| Industrial applicability (IA) | Claims | 1-20, 22-24 | YES |
| | Claims | | NO |

2. Citations and explanations

Document 1: T. AZUMA et al., Br. J. Haematol., 2002, Vol. 116, No. 3, pages 601-603

Document 2: WO 00/18795 A2 (Coriza Corp.), 06 April 2000

Document 3: Akihiro TSUBOI et al., "Hito WT1 Kaihen Peptide wo Mochiiru koto ni yoru, WT1 Tokui-teki CTL Yuudou-nou no Zoukyou," Nippon Meneki Gakkai Soukai, Gakujutsu Shuukai Kiroku, 2001, Vol. 31, page 160

Claims 3 and 16-20 lack novelty and do not involve an inventive step in the light of document 1 cited in the international search report. Document 1 indicates a HLA-A24-restricted peptide with an activity whereby it induces CTLs, which comprises a modified amino acid sequence that includes modifications to the amino acid residues of the amino acid sequence represented by SEQ ID NO: 4.

Claims 1-20 and 22-24 do not involve an inventive step in the light of document 2 cited in the international search report and newly cited document 3. Document 2 discloses peptides derived from WT1, which comprise the amino acid sequences represented by SEQ ID NO: 7, 8, 9, 51 and 52 of the present application. Document 3 indicates that modifying the P2 site of a peptide derived from WT1 with tyrosine will augment the function whereby the

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peptide induces WT1-specific CTLs; therefore, a person skilled in the art could easily produce a modified peptide wherein the P2 sites of the abovementioned peptides that are disclosed in document 2 have been modified with tyrosine.